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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/908,070	07/18/2001	Dachuan Yang	S63.2-9826	7520

490 7590 03/21/2005

VIDAS, ARRETT & STEINKRAUS, P.A.  
6109 BLUE CIRCLE DRIVE  
SUITE 2000  
MINNETONKA, MN 55343-9185

EXAMINER

BAXTER, JESSICA R

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 03/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	<b>Application No.</b> 09/908,070	<b>Applicant(s)</b> YANG ET AL.	
	<b>Examiner</b> Jessica R Baxter	<b>Art Unit</b> 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 January 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3-14 and 39-43 is/are pending in the application.
- 4a) Of the above claim(s) 41-43 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 12-14 is/are allowed.
- 6) ☒ Claim(s) 1,3-11,39 and 40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 3, 2005 has been entered.

### ***Election/Restrictions***

2. Newly submitted claim 43 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the new claims are of a different species than previously claimed. A different lubricant is being claimed that was not previously claimed is now being claimed.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 41 and 42 withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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4. Claims 1, 3, 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tingey et al. '840 in view of U.S. Patent No. 5,082,630 to Partin et al.

Tingey discloses a method for detecting the presence and uniformity of a lubricious coating on a medical device comprising the steps of preparing a mixture of at least one fluorescing agent and at least one lubricant; applying said mixture to the surface of a medical device, subjecting the surface of the medical device to a source of energy capable of inducing a fluorescing emission; and observing the fluorescent emission (Column 2 line 64-Column 3 line 7). Tingey discloses the claimed invention except for the specific fluorescing agent being a fluorescein or a rhodamine. Partin teaches that fluorescein and rhodamine are fluorescent dyes that have good absorption and fluorescent yield characteristics that provide high sensitivity. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device, of Tingey with a rhodamine or a fluorescein fluorescent agent since these agents have good absorption and fluorescent yield characteristics.

Regarding claims 3 and 4, Tingey discloses that said fluorescing agent is a fluorescein, triarylmethane, rhodamine, a derivative thereof, and mixtures thereof (Column 3 lines 56-61) and said hydrophilic dye is 5-carboxyfluorescein, 6-carboxyfluorescein, fluorexon, lissamine green, indocyanine green, rose bengal or mixture thereof (Column 4 line 56-Column 5 line 16).

Regarding claim 5, Tingey discloses that said hydrophobic lubricant is a silicone based lubricant (Column 3 lines 56-61).

Regarding claim 6, Tingey discloses that said hydrophobic lubricant is a polydimethylsiloxane (Column 3 lines 56-61).

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5. Claims 4, 39 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tingey et al. '840 in view of Partin et al., as applied above, and further in view of U.S. Patent No. 5,346,689 to Peyman et al.

Tingey, as modified, discloses the claimed invention except for the specific fluorescing agent being a carboxyfluorescein. Peyman teaches that carboxyfluorescein is a hydrophilic derivative of fluorescein that is well known in the art to be used in applications to blood vessels that require fluorescent agents (Column 1 lines 42-58). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Tingey, as modified, with the fluorescing agent of a carboxyfluorescein since it is well known to be used in the surgical arts.

6. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tingey et al. '840 in view of Partin et al. '630, as applied above, further in view of U.S. Patent No. 6,254,634 to Anderson et al.

Tingey, as modified discloses the claimed invention except for the use of a lubricant in combination with a crosslinkable silicone. Anderson teaches that an intermediate layer of crosslinkable silicone is provided with a coating in order to improve the performance and durability of the coating by preventing the lubricant from being wiped off the surface of the coated device (Column 2 lines 54-59, Column 3 lines 41-62 and Column 5 lines 42-64). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the method of Tingey, as modified, with the crosslinkable silicone in order to improve the durability of the coating on the medical device.

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7. Claims 8-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tingey et al. '840, in view of Partin et al. '630, as applied above, further in view of U.S. Patent No. 5,266,359 to Spielvogel.

Tingey, as modified, discloses the claimed invention except for the mixture further comprising a surfactant. Spielvogel teaches that a surfactant may be added to a medical device in order to improve the lubriciousness of the device (Column 2 lines 49-56 and Column 4 lines 38-52). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Tingey with the surfactant of Spielvogel in order to improve the lubricity of the device.

### ***Response to Arguments***

8. Applicant's arguments filed January 3, 2005 have been fully considered but they are not persuasive.

9. Applicant argues that Tingey et al. '840 discloses that the fluorescent agent must have a degree of solubility in polydimethylsiloxane. Applicant discloses that it is difficult to dissolve the dye directly in polydimethylsiloxane (Paragraph 55). Applicant admits that the chosen dyes have a degree of solubility in polydimethylsiloxane since it is said to be difficult, but not impossible to dissolve the preferred dyes in polydimethylsiloxane. Tingey et al. '840 also discloses that other dyes than those listed may be used (Column 4 line 56-Column 5 line 16). Since applicant has admitted that the preferred dyes have a degree of solubility in polydimethylsiloxane, the method of Tingey could be used with dyes as claimed by applicant.

10. Applicant argues that Spielvogel '359 has been misunderstood by the examiner. It is not clear what has been misunderstood. It appears it is the function of the surfactant.

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11. In response to applicant's argument that Spielvogel '359 teaches a surfactant for emulsification instead of for improving lubriciousness, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

***Allowable Subject Matter***

12. Claims 12-14 are allowed.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica R Baxter whose telephone number is 571-272-4691. The examiner can normally be reached on M-F 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan T Nguyen can be reached on 571-272-4963. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Jessica R Baxter  
Examiner  
Art Unit 3731

*JRB*  
jrb

March 14, 2005

*ANHTUAN T. NGUYEN*  
ANHTUAN T. NGUYEN  
SUPERVISORY PATENT EXAMINER

*3/17/05*